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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,081	11/16/2000	Joaquin Villalobos	CRD-726	5133

7590 01/16/2004
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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/16/2004

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/714,081

Applicant(s)

VILLALOBOS ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments filed August 20, 2003 have been fully considered but they are not persuasive. Applicant has argued that there is no motivation to combine the reference Rasmussen (USPN 5,324,304) with Palestrant (USPN 4,832,055) because Rasmussen does not have a need for a stop and that there is no motivation in Palestrant to use a stop with Rasmussen. The examiner disagrees. Rasmussen discloses a stent delivery system comprising an inner catheter shaft and outer sheath. Although Rasmussen does not disclose a stop located on the inner catheter shaft, stops are well known in the art for use in catheter delivery systems and Palestrant is one who teaches use of a stop on delivery systems. Palestrant uses a stop on an inner catheter shaft for the purpose of creating a predetermined distance temporarily between the end of the stop and the outer sheath allowing the surgeon to retract the outer sheath a predetermined distance in order to partially deploy the stent when in position and, which later the stop may be removed when the surgeon is ready for full deployment. The stop also allows premature full deployment so that the stent does not fully deploy before the stent is at the proper location in the body, at this point the safety stop may be finally removed (col.15 line 62-col.16 line 24). Palestrant's teaching of using removable stops on catheter systems is applicable to all stent delivery systems having an inner catheter and outer sheath, including Rasmussen's stent delivery system. The rejection still stands.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen (USPN 5,324,304, cited in previous office action) in view of Palestrant (USPN 4,832,055, cited in first office action). Referring to claims 1, 4, and 13, Rasmussen discloses a delivery apparatus comprising an outer sheath (5), an inner shaft (8, 10) coaxially positioned within the sheath (5), wherein the inner shaft (8) further comprises at least two grooves (14), and a self-expanding stent (1; col.1, lines 5-10) having at least two legs (2) attached to the proximal end of the stent, extending proximally, each leg having a flange (4), wherein flanges (4) are set within grooves (14) releasably attaching the stent (1) to the shaft (8, 10). Rasmussen does not disclose however, a stop releasable affixed to the inner shaft. Palestrant teaches in the same field of self-expanding stent delivery apparatus, attaching a releasable affixed stop (291) to the exterior surface of an inner shaft (280), the stop having an outer diameter larger than an inner diameter of an outer sheath (270) in order to define a fixed space and limit movement between the outer catheter and stop, allowing a predetermined amount of partial deployment (col.15, line 62- col.16, line 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Palestrant's teaching of use of a releasable stop member on an inner shaft of a delivery apparatus, with the stent delivery apparatus of Rasmussen in order to allow a predetermined amount of partial deployment.

Referring to claim 5, Rasmussen discloses a self-expanding stent, however does not explicitly disclose the material the stent is made of. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the self-expanding stent out of superelastic Ni-Ti alloy, a known self-expanding material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Referring to claim 7, Rasmussen discloses flanges (4) that fit completely within the grooves (14), (col.2, lines 30-32; col.4, lines 29-34; col.5, lines 49-54).

Referring to claims 8 and 10, Rasmussen discloses legs that are equally spaced apart and extend distally and axially away from the self-expanding stent (fig.4, 6, 8).

Referring to claims 6, 9, and 11, Rasmussen discloses legs having bent L-shaped flanges and line slit grooves in the inner shaft. Rasmussen does not disclose expressly I or T shaped flanges or grooves. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to create an I or T shaped groove/flange because Applicant has not disclosed that an I or T shaped flange or groove provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with L shaped flanges/grooves because any flange will fit within a corresponding groove providing a low profile diameter, regardless the shape of the flange/groove. Therefore, it would have been an obvious matter of design choice to modify Rasmussen to obtain the invention as specified in claims 6, 9, and 11.

Claims 2, 3, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen (USPN 5,324,304, cited in previous office action) in view of Palestrant (USPN 4,832,055, cited in a previous office action) as applied to claims 1 and 4 above, and in further view of Johnson et al. (USPN 6,136,006, cited in previous office action). Rasmussen discloses a self-expanding delivery apparatus and Palestrant teaches the use of a releasably affixed stop member (291) on the delivery apparatus (figs.11-15; col.15, line 62- col.16, line 15). Palestrant does not however, clearly show the details of the shape of the stop or how exactly the stop is releasably affixed to the catheter. Johnson teaches in the same field of delivery apparatus and stop members, a releasably affixed stop member (76) that is semi-cylindrical and snap fits over an inner shaft (26), providing a means for removal of the stop (col.7, lines 1-3), and the stop having an outside diameter larger than an inner diameter of an outer shaft (18) so that the outer sheath

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abuts the stop, limiting the amount of movement of the outer sheath (18) relative to the inner catheter (26; col.6, lines 63-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Johnson's teaching of specific size and snap fit shape for a stop member with the stent delivery apparatus with releasable stop member of Rasmussen in view of Palestrant's in order to provide a means for limiting the amount of movement of an outer sheath relative to an inner catheter when the stop is affixed and provide a means for removal of the stop, at the time of full deployment.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Cheryl Miller


BRUCE SNOW
PRIMARY EXAMINER